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(57) A tampon 1 especially for use with anal incontinence is made of PVA which is immunologically safe, and has a spherically thickened distal end 3 which lies inside the body in use and aids sealing.

In a further embodiment the tampon also has a concave body which corresponds to the convex shape of the anal channel of certain patients.

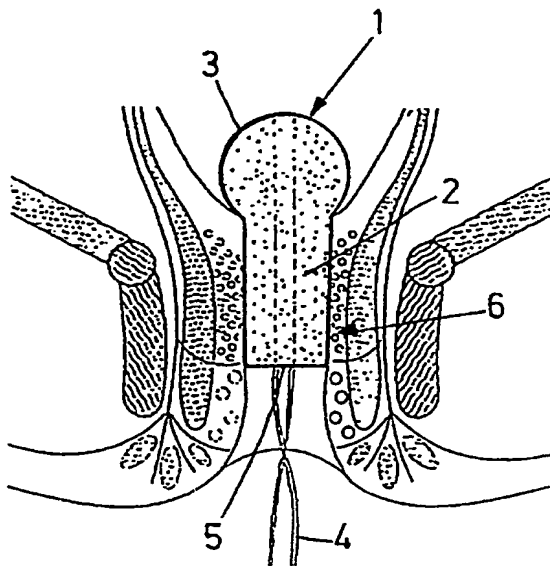


FIG. 1

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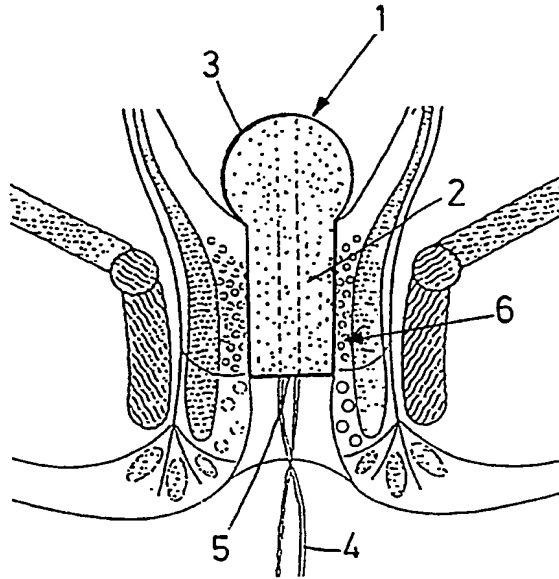


FIG. 1

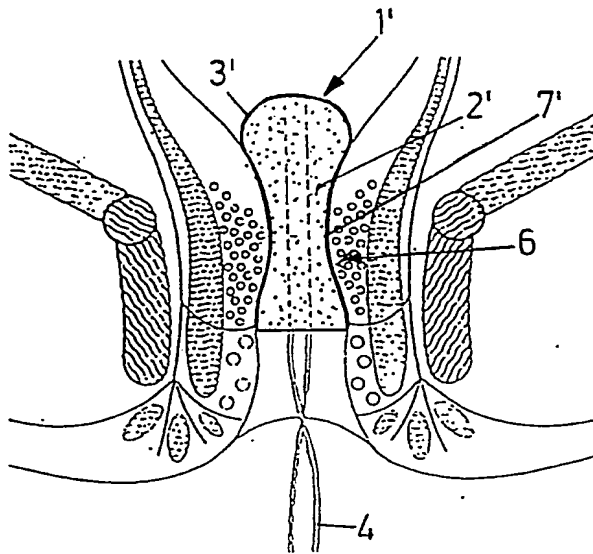


FIG. 2

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## **TAMPON, ESPECIALLY ANAL TAMPON**

The invention relates to a tampon, especially an anal tampon, serving as a temporarily usable rectum closure in case of anal incontinence.

The organic causes of anal incontinence may result from a functional restriction or a defective position of neurogenic or myogenic elements.

The meningocele, which belongs to the most frequent forms of disturbance in the anal sphincter region, appears with persons who are taken ill with spina bifida. This form of disease also often leads to the formation of hydrocephalus.

Apart from congenital anal incontinence there are also acquired forms, which for instance may be a consequence of tumors in the region of the rectum or in the channel of the spinal cord. In addition, there are several cases of incontinence, which appear as a consequence of operations. So, the risk of incontinence exists with operations such as the pull-through procedure, the deep resection or also the sphinctermyotomia.

With the above considerations in mind it is the object of the invention to meet incontinence with conservative therapeutical measures while avoiding operative measures and all this in a manner which is easy to handle for the patient and which is extremely effective in its result.

This object is attained by an anal tampon, which has a basic body of PVA and wherein the end lying inside during use is formed in thickened manner in relation to the basic body.

With a first preferred embodiment the basic body may be formed cylindrically and the thickening may be formed spherically. A second embodiment provides that the thickening is also formed spherically, the basic body, however having a concave necking.

An anal tampon made of PVA consists of a dermatologically and toxicologically unrisky and immunologically inactive special made foamed material, which is kind to the mucous membrane.

Highly sensitive mucous membrane regions in the anal channel necessitate this material to be used as a high-quality basic raw material, as due to the difficulties with the toxicological precariousness from the medical view one cannot return to cost-effective industrial foamed material.

Long term tests and clinical tests have shown that even if used as an implant there are no reactions of the immune system.

Tampons according to the invention are manufactured with different diameters and lengths, in order to permit optimum adaptation to the individual conditions of the respective user.

In a further embodiment of the invention the tampons have an internal bore for receiving an insertion rod. Furthermore, a withdrawal cord may be provided. The latter makes a safe removal after use possible without any problems.

The above described first embodiment with a cylindrical basic body is suitable above all for patients, who still have residual functions of the muscular region, but who have no sealing and holding function ensured due to a weak formation of the tissue. For such patients the tampon permits a muscular training, e.g. in form of an interval compression training, so that the residual function of the sphincter is strengthened to such a degree that a self-controlled domination of the sphincter can again be attained.

For anal incontinent patients, who have no residual function at all of the muscular tissue and whose anal channel has a smooth muscular apparatus, it is provided that on the cylindrical basic body a spherical cupula is arranged, which comes to rest in the region of the ampulla-recti, the anal tampon acting as a kind of spherical valve and ensuring

the desired reliable sealing.

The second embodiment according to the invention with a concave basic body is designed for such patients, who have a corresponding convex formation of the muscular tissue. By means of the necked tampon shape a holding and sealing function is permitted in the anal channel.

In the following an anal tampon according to the invention is further described on the basis of two preferred embodiments taken in conjunction with the drawing, in which

Fig. 1 shows an anal tampon according to the invention in accordance with a first embodiment in situ and

Fig. 2 shows a corresponding illustration of a second embodiment.

An anal tampon 1 shown in Fig. 1 comprises an approximately cylindrical basic body 2 and an approximately spherical thickening 3 towards the inner side. A withdrawal cord 4 permits withdrawal after use, whereas at 5 a bore not shown in detail in the drawing is provided for an applicator for inserting the tampon.

This embodiment of the tampon 1 is suitable in case there is no formation of the sphincter in the rectum region 6, so that safe holding of the tampon 1 must be performed by the spherical cupula 3.

In Fig. 2 a further embodiment of a tampon 1' according to the invention is shown, which in fact comprises also a thickening 3' on the inner side, the basic body 2' of which, however, comprising a convex necking 7'.

This embodiment of the tampon 1' is used in case the rectum region 6 is in principle normally formed. The sphincter adapts in this case to the shape of the tampon 1', so that the latter is optimally sealed and fits safely.

In the foregoing the invention was described taken in conjunction with an anal tampon explained in the example of embodiment. The embodiment according to the invention, however, may be realized with equal advantage also in form of a vaginal tampon. The purpose of intravaginal insertion in this case is to support the weakened pelvic muscular apparatus. On this occasion it is also possible to insert therapeutically effective preparations, if necessary, together with the tampon.

Patent claims

1. Tampon, especially anal tampon, wherein it is made of PVA, the end lying inside during use being formed in thickened manner in relation to the basic body.
2. Tampon, especially anal tampon according to claim 1, wherein the basic body is formed cylindrically and the thickening is formed spherically.
3. Tampon, especially anal tampon according to claim 1, wherein the thickening is formed approximately spherically and the basic body comprises a concave necking.
4. Tampon, especially anal tampon according to claim 1, wherein it is provided with a withdrawal cord.
5. Tampon, especially anal tampon according to claim 1, wherein it is provided with a recess for an insertion aid.
6. Tampon, especially anal tampon, substantially as hereinbefore described and with reference to the accompanying drawings.

**Relevant Technical Fields**

- (i) UK Cl (Ed.N)      A5R RPQ RPT
- (ii) Int Cl (Ed.6)      A61F 13/20 A61F 13/22 13/24 A61L 15/22  
15/24

Search Examiner  
MR S J PILLING

Date of completion of Search  
6 FEBRUARY 1995

**Databases (see below)**

- (i) UK Patent Office collections of GB, EP, WO and US patent specifications.

Documents considered relevant following a search in respect of Claims :-  
1-6

- (ii) ONLINE DATABASE WPI

**Categories of documents**

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| <b>A:</b> Document indicating technological background and/or state of the art.   | <b>&amp;:</b> Member of the same patent family; corresponding document.   |

Category	Identity of document and relevant passages		Relevant to claim(s)
Y	GB 1146293	(KIMBERLY-CLARK) page 1 lines 10 to 12 and page 4 lines 44 to 50	1, 2, 4 and 5
Y	GB 726016	(KRAMER) page 1 line 49 to 52 and Figure 2	1
Y	GB 527827	(GALWAY) page 1 lines 54 to 69 and Figure 2	1, 2, 4 and 5
Y	EP 0001746 A1	(WIEGNER ET AL) see enclosed abstract and Figure 7	1, 2, 4 and 5
Y	WO 88/10106 A1	(PROSTHEX) page 4 lines 4 to 13	1, 2, 4 and 5
Y	US 4251643	(HARADA & YOSHITAKE) column 2 lines 22 to 34	1, 2, 4 and 5

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